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Dated: June 4, 2007    Signature: /Jeanne M. Brashear/  
(Jeanne M. Brashear)

Docket No.: 13024/38627A  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
McMichael et al.

Confirmation No.: 6871

Application No.: 10/624,328

Filed: July 22, 2003

Art Unit: 1614

For: Method of Treatment of Psychological Conditions    Examiner: D.C. Jones  
by Administration of Nerve Growth Factor

**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

MS AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Applicants request review of the Final Office action in the above-identified application. No amendments are being filed with this request. This paper is timely filed in view of the petition for a one-month extension of time and fee submitted herewith. See M.P.E.P. § 706.07(f).

This paper is filed concurrently with a Notice of Appeal and fee, and includes no more than five pages of arguments for patentability. It follows a Final Office action dated January 22, 2007, and a response to the final action dated March 22, 2007, that failed to resolve patentability questions. Reconsideration is respectfully requested in view of the following remarks.

**Remarks** begin on page 2 of the paper.

## **REMARKS**

### **I. BACKGROUND**

The present invention is directed towards methods of treating psychological conditions. Applicants discovered that administering nerve growth factor alleviates one or more symptoms associated with various psychological disorders selected from the group consisting of depression, anxiety disorders, panic attacks, premenstrual dysphoric disorder (PMDD), and premenstrual syndrome (PMS).

### **II. THE OBVIOUSNESS REJECTION OVER FREY II IN VIEW OF BEERS SHOULD BE WITHDRAWN.**

The rejection of claims 1, 2, 4, 5, 8-18 and 20-24 as being obvious over Frey II (U.S. Patent Publication No. 2003/0072793) in view of Beers (The Merck Manual of Diagnosis and Therapy, 17<sup>th</sup> Edition, pages 1525-1539 and 1932-1933, 1999) should be reversed because Frey II is directed to a mode of drug administration and not to methods of disease treatment and does not disclose or suggest the administration of NGF for the treatment of psychological disorders.

#### **A. Frey II fails to disclose or suggest the administration of NGF for the treatment of psychological disorders.**

Frey II is directed to a particular method of administering an agent to the central nervous system (CNS) of a subject. Frey II exemplifies its methods by demonstrating the administration of Insulin-like Growth Factor (IGF-I) to a tissue innervated by the trigeminal nerve but does not teach a treatment of any particular disease state with IGF-I. Frey II does provide a laundry list of forth-plus (40+) agents (para. 0036-0104) that can be administered by its method and also provides a laundry list of seventeen (17) conditions (para. 0169) that such agents may be administered for. These lists are not prescriptive, however.<sup>1</sup> Indeed, most of the forty-plus agents listed would not be expected to be therapeutic for most of the seventeen or more conditions listed in paragraph 0169. Some combinations of agent and condition may also be contraindicated. Accordingly, one of skill in the art would not have concluded which one of the many “agents” disclosed in Frey II could be used to alleviate one or more symptoms of a psychological disorder.

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<sup>1</sup> There are at least 680 different therapeutic agent/CNS disorder combinations implied by the Examiner’s argument.

Beers, a textbook for the diagnosis and therapy of various disorders, does not provide the necessary disclosure lacking from Frey II. Beers does not disclose or suggest the use of NGF for the treatment of the disorders recited in the claims. Consequently, Beers fails to make up for the deficiencies of Frey II (i.e., method of alleviating one or more symptoms of a psychological disorder by administering NGF).

### **III. THE OBVIOUSNESS REJECTION OVER SIUCIAK IN VIEW OF BEERS SHOULD BE WITHDRAWN.**

The rejection of claims 1, 2, 4, 5, 11-15 and 20-24 as being obvious over Siuciak (U.S. Patent No. 5,599,560) in view of Beers, *supra*, should be reversed because NGF is a different protein than brain-derived neurotrophic factor (BDNF), neurotrophin-3 (NT-3) and neurotrophin-4 (NT-4) disclosed by Siuciak for treatment of depression. Moreover, NGF cannot be expected to exhibit the same biological activities as BDNF, NT-3 and NT-4 because Siuciak itself emphasizes that NGF lacks some of the beneficial biological effects of BDNF, NT-3 and NT-4 (col. 3, lines 11-14). Moreover, Siuciak does not disclose or suggest the use of NGF for the treatment of any disorder, let alone the psychological disorders recited in the claims.

#### **A. Siuciak teaches away from the claimed invention because Siuciak emphasizes the different biological activities of NGF when compared to BDNF, NT-3 and NT-4 and fails to disclose or suggest the administration of NGF for the treatment of any disorder.**

At column 3, lines 11-14, Siuciak refers to a study by Friedmann et al. (Exp. Neph., 119:72-78, 1999, submitted in response to the Final Office action mailed January 22, 2007 as Exhibit A) which reports that members of the NGF family of neurotrophins exhibit different biological activities. (See, for example, Friedmann et al. page 76, second column, first paragraph).

Specific neurotrophins such as NT-3 and NT-4 enhanced survival of both neuronal populations [locus coeruleus (LC) and basal forebrain (BF)]. **NGF, which has no effect on LC neurons**, influenced the BF by increasing cholinergic function but not survival, **in contrast to BDNF, NT-3, and NT-4**. (emphasis added.)

Accordingly, one of skill in the art would not have concluded from Siuciak that NGF could be expected to have the same biological activity as BDNF, NT-3 and NT-4. Similarly, one of skill on the art would not have concluded from Siuciak that NGF could be

used as a therapeutic in disorders normally treated with BDNF, NT-3 or NT-4 and would not be motivated upon review of Siuciak to use NGF to alleviate the symptoms of the psychological disorders recited in independent claims 1 or 15.

Again, Beers is merely a textbook for the diagnosis and therapy of various disorders and does not provide the necessary disclosure lacking from Frey II. Beers does not disclose or suggest the use of NGF for the treatment of the disorders recited in the claims. Consequently, Beers fails to make up for the deficiencies of Siuciak (i.e., method of alleviating one or more symptoms of a psychological disorder by administering NGF).

Finally, it should be noted that in response to the Office action mailed April 27, 2006, Applicants did not “argue that NGF illustrates typical qualities of neurotrophic factors and neurotrophin family” as asserted by the Examiner. In contrast, Applicants stated that NGF is a different protein than BDNF, NT-3 and NT-4.

#### **IV. CONCLUSION**

In view of the foregoing, Applicants respectfully submit that the Examiner has erred and that the panel should allow currently pending independent claims 1 and 15 (and all claims dependent thereon). The Patent Office is authorized to charge any fees due in this case to Deposit Account No. 13-2855, under reference number 13024/38627A. The Applicants claim small entity status for such fees.

Dated: June 4, 2007

Respectfully submitted,

By /Jeanne M. Brashear/

Jeanne M. Brashear

Registration No.: 56,301

MARSHALL, GERSTEIN & BORUN LLP

233 S. Wacker Drive, Suite 6300

Sears Tower

Chicago, Illinois 60606-6357

(312) 474-6300

Agent for Applicants